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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/856,341

Applicant(s)

BEIER, MA

Examiner

Jennifer Kolb Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,9,11-13,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,9,11-13,20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Examiner acknowledges Applicant's election of Group I, claims 1-13 and newly added claims 20-21. Cancellation of non-elected claims 14-19 is acknowledged with appreciation. With amendment B, paper 10, of 6/12/2003, Examiner additionally acknowledges the cancellation of claims 4-7 and 10. Claims 1-3, 8-9, 11-13, and 20-21 are pending for examination below.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on June 8, 2001 has been considered by the Examiner.

### ***Specification***

3. The use of the trademarks Teflon and Jeffamine has been noted in this application (instant specification, page 5). They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. Examiner suggests the use of headings within the specification. For example, at the bottom of page 16, prior to a discussion of the drawings, a heading of "Brief Description of Drawings" is suggested.

### ***Examiner's Suggestions/Interpretations***

5. Claim 1 is a method directed to "functionalizing a support", which requires activating a functional group *which is said to be present already* on the support, then adding a polyamine. It appears that the support of claim 1 is already functionalized and that the claimed invention is truly directed to aminating the substrate via activation of the already functionalized support. For consistency, Examiner suggests the preamble of the claim be amended to require —aminating— or —derivitizing—or the like. Once consistent language is chosen for claim 1, Examiner suggests claims 12 and 13 maintain that consistency.

6. Claim 1 requires the use of a chemical "EDC" on line 6, with a parenthetical requirement of the specific chemical formula desired. EDC contains a group of very similar chemicals, including that which is listed in parentheses. The claim has been interpreted to be inclusive of any EDC, as broadly required before narrowing that range to that which is disclosed within the parentheses.

7. Claim 21 depends on claim 2, which requires a selection of support surfaces, one choice being cellulose derivatives. Dependent claim 21 further limits the cellulose

derivative limitation when "cellulose derivatives" is chosen from the Markush group of claim 2. Since claims 2 and 21 do not further require cellulose derivatives be chosen, claim 21 is not interpreted as requiring the use of the stated derivatives unless cellulose derivatives are the chosen substrate material of claim 2. A 102 rejection would apply to claim 21 so long as cellulose derivatives are not chosen from the Markush group of claim 2.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the trademarked product "Teflon".

The recitation of Trademarks renders the claim indefinite because it does not indicate whether the same material made under a different Trademarked product is equally operational. Moreover, the value of the Trademark is lost to the extent that it becomes descriptive of a product rather than the identification of a source or an origin of a product.

Claim 12 requires the functionalized surface of claim 2 to be "additionally activated prior to the attachment of biopolymers". Claim 2 recites a list of suitable support substrates

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and depends on claim 1, which requires a "method of functionalizing a support, comprising the steps of: activating a functional group on a support", as outlined above.

Since claim 1 already requires activation of the functionalized surface, the phrase "additionally activated" is unclear for the following reasons.

Because claim 1's preamble is directed to functionalizing a surface, which is later said to be functionalized already, it is not clear whether the activating step of claim 12 requires activation of the original functionalized surface, or the surface of the support after the method steps of claim 1 are complete. If Examiner's Suggestions are followed, above, regarding the preamble of claim 1, claim 12 may become more clear.

Furthermore, it is not clear whether an additional activation step is required at all. Claim 12 can be read to merely require that, in *addition* to the activation of claim 1, biopolymers are attached. Due to the confusion regarding to which functionalized support Applicant is referring, for the purposes of examination, Examiner has interpreted claim 12 to merely requires that, in addition to and following the activation step of claim 1, biopolymers are attached.

This is a reasonable interpretation of claim 12 in light of claim 13 which requires the activating agent of claim 12 to be one selected from a smaller group, similar to that of claim 1, indicating that it is not a new activation step that is added in claim 12, but a biopolymer attachment step.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 8, 9, 11-13, and 20-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Beier et al. (Nucleic Acids Research, vol. 27, number 9).

In one embodiment Beier teaches treating glass slides or polypropylene sheets, which contain functional amine groups, with 4-nitrophenyl-chloroformate or acryloylchloride (p. 1971, col. 1), meeting the activating agent requirement of claim 1. 4-nitrophenyl-chloroformate or acryloylchloride activates, by acylation, the amine functional groups on the support surface (see also page 1972, col. 2, 1<sup>st</sup> paragraph, line 4). Subsequently, Beier teaches that the activated functional group is reacted with a polyamine component, such as tetraethylene pentamine, among others. Figure 2 shows the production of a dendrimeric structure using the method of Beier, which is defined in the art as a highly branched polymeric structure. Additionally, the creation of a dendrimeric structure is inherent in the method of Beier because all of Applicant's method limitations are met by Beier. Therefore if there is some difference between Applicant's structure and Beier et al.'s, it must be due to some process limitation not present in Applicant's claims.

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Regarding claim 2, Beier teaches the use of glass or polypropylene substrates as outlined above.

Regarding claim 3, Beier teaches the presence of amine functional groups on the support substrate, as outlined above.

Regarding claim 8, Beier teaches the polyamine tetraethylene pentamine, as outlined above, among others.

Regarding claim 9, the reaction between the activating agent and polyamine is done serially and repeated by Beier (p. 1972, col. 2, 1<sup>st</sup> paragraph, line 3).

Regarding claim 11, a positive charge is built up in a controlled fashion by Beier (p. 1972, col. 2, 2<sup>nd</sup> paragraph, line 2).

Regarding claim 12, as interpreted above, Beier teaches attachment of biopolymers to the aminated surface above (p. 1973, col. 2, 2<sup>nd</sup> paragraph).

Regarding claim 13, Beier teaches various activation reagents including phenylendiisothiocyanate (col. 2 of p. 1971).

Regarding claim 20, Beier teaches a biochip support (p. 1974, col. 1).

Regarding claim 21, since Applicant does not require selection of cellulose derivates in claim 2, on which claim 21 depends, Beier meets the limitations of this claim for those reasons outlined in the Interpretations section.

12. Claims 1-3, 11-12, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al. (US 5,607,475).

Cahalan teaches treating a medical device containing carboxyl groups thereon with an activating agent to activate said carboxyl groups. The activating agent of Cahalan is 1-ethyl-3-(3-dimethyl-aminopropyl) carbodiimide hydrochloride, or EDC, as required by claim 1. The activated functional group of Cahalan is further reacted with a polyamine (col. 7, lines 3, 10, 15-17).

The creation of a dendrimeric structure is inherent in the method of Cahalan because all of Applicant's method limitations are met by Cahalan. Therefore if there is some difference between Applicant's structure and Cahalan's, it must be due to some process limitation not present in Applicant's claims.

The substrate of Cahalan may be glass (abstract), as required by claim 2.

The functional groups of the substrate of Cahalan are carboxyl, as required by claim 3.

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Regarding claim 11, the polyamine inherently provides positive charge to the substrate.

Cahalan inherently "controls" his method using the method steps he outlines.

Cahalan attaches biomolecules to the functionalized, activated, aminated substrate (col. 7, line 27), as required by claim 12. One example provided is heparin, which is a natural polymer.

Claim 21 is included herein for those reasons outlined in the Interpretations section.

13. Claims 1-3, 11-12, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolowitz et al. (4,837,348).

Stolowitz teaches treatment of glass supports with amine groups thereon, by activating the amine groups via the activating agent carbonyldiimidazole followed by reacting the activated surface with a polyamine, as required by claim 1 (abstract).

Formula VI in col. 5 appears to show a dendrimeric structure.

Additionally, the creation of a dendrimeric structure is inherent in the method of Stolowitz because all of Applicant's method limitations are met by Stolowitz. Therefore if there is some difference between Applicant's structure and Stolowitz's, it must be due to some process limitation not present in Applicant's claims.

As outlined above, the support may be made of glass, as required by claim 2, with amine groups thereon, as required by claim 3.

Regarding claim 11, the polyamine inherently controllably provides positive charge to the substrate.

Regarding claim 12, Stolowitz teaches attachment of a bio macromolecules, which are polymeric as seen from formula VII.

Regarding claim 20, the substrate of Stolowitz is a biochip by definition, as a biochip is a miniature support to be used in binding and/or assaying of oligonucleotides, polynucleotides, and the like (See abstract, last line; col. 1, line 25; col. 5, line 36).

Claim 21 is included herein for those reasons outlined in the Interpretations section.

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tsubokawa (Reactive & Functional Polymers 37 1998) teaches creating a dendrimer polymer on a silica surface containing functional amine groups by activating the amine surface groups followed by addition of a polyamine. The reference fails to teach the activating reagents of Applicant.

Yang et al. (U.S. Pat. 6,509,059 B2) teach coating medical devices with dendrimeric coatings (see Figures) of spermine and spermidine using an activating agent such as

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carbodiimides or chloroformates (col. 9, lines 1-10), but fail to teach the specific agents of Applicant.

Verhoeven et al. (US 5,672,638) teaches coating a cellulose substrate with EDC crosslinked with polyamine for subsequent application of biomolecules.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The Examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



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June 29, 2003